DEC 15 2000

K003770

510(K) SUMMARY

TBird Legacy Ventilator

Bird Products Corporation

Tom Gutierrez
Regulatory Compliance Engineer
Bird Products Corporation
1100 Bird Center Drive
Palm Springs, CA 92262-6267

(760) 778-7225 (phone)
(760) 778-7274 (fax)
August 11, 2000

K003770

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Manufacturing Site:	Bird Products Corporation 1100 Bird Center Drive Palm Springs, CA 92262
Contact:	Tom Gutierrez (760) 778-7255 (phone) (760) 778-7274 (fax)
Summary Date	August 11, 2000
Device Trade Name:	TBird Legacy Ventilator
Device Common/Classification Name:	Classification name: 868.5895 Continuous Ventilator, 73 CBK
Establishment Registration Number	2021710
Device Class:	Class II
Classification Panel:	Anesthesiology
Predicate Device:	The predicate devices are: TBird Homecare Ventilator, FDA 510(k) No: K981971 TBird VS, AVS Volume Ventilator FDA 510(k) No: K950484 Smartvent 201 Portable Ventilator FDA 510(k) No: K981668
Device Description:	The TBird Legacy Ventilator employs a turbine gas delivery system along with microprocessor control to provide support for pediatric to adult patients. Capable of delivering clinically advanced modes of ventilation like Pressure Support with an internal battery or AC power the TBird Legacy Ventilator has an extensive patient range. The TBird Legacy Ventilator ventilator pneumatic system is an electromechanical system comprised of four major subsystems, each containing several components. These systems include the flow delivery system, the exhalation system, the safety system and the inspiratory hold valve. This electromechanical system controls all inspiratory flow to the patient. The exhalation system controls the flow of gas from the patient's lungs during the exhalation phase. The mechanical safety system ensures that the patient can breath spontaneously from room air and that the patient pressure is limited to a maximum value in the event of a ventilator malfunction. When activated, the inspiratory hold valve blocks flow between the flow delivery system and the patient. The TBird Legacy Ventilator ventilator electronic system is comprised of several subsystems, each containing numerous components. These subsystems include the Display System, the Power System, the Main Controller System, Exhalation, and Flow Delivery systems. The Display System is comprised of three Alarm Setpoint Displays, seven Control Setpoint Displays, up to forty-eight Message Display characters, up to twenty-five Discrete Indicators, and a bargraph style Manometer. The Main Controller System is comprised of three Pressure Transducers, an Analog-to-Digital Converter, two Digital-to-Analog Converters, the Input-Output Processor, Solenoid Valves, and the Watchdog and Hardware Fault Monitors. The Power System conditions and controls energy from the AC line input, the internal battery, and the optional external battery pack. When energy is available from the AC line, the ventilator operates from this source, as well as recharging the internal battery and the external battery (if present).

Intended Use:

The TBird Legacy Ventilator is intended to provide continuous or intermittent mechanical ventilatory support for the care of individuals who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 10 kg (22 lbs.), who require the following general types of ventilatory support, as prescribed by an attending physician:

- Positive pressure ventilation
- Assist/Control, SIMV, CPAP modes of ventilation

The ventilator is suitable for use in institutional, home, and transport settings. It is not intended for use as an emergency medical transport ventilator

Substantial Equivalence

The TBird Legacy Ventilator is the same device as the TBird Homecare Ventilator, which was cleared for market under 510(k) K981971. The name of the device was changed to the TBird Legacy.

Two modifications to the TBird Legacy Ventilator are associated with this submittal.

- The Pressure Control mode of ventilation is being added.
- A High Breath Rate Alarm is being added.

The modified TBird Legacy Ventilator have the following similarities to those which previously received 510(k) concurrence:

- have the same indicated use,
- use the same operating principle,
- incorporate the same basic design,
- incorporate the same materials, electrical/electronic and mechanical components
- are manufactured and packaged utilizing the same materials, components and processes.

- In summary, the TBird Legacy Ventilator described in this submission is, in our opinion, substantially equivalent to the predicate device(s).

Summary of Testing and Validation:

Performance testing verified that the TBird Legacy Ventilator Ventilator meets it's performance requirements and that this device is substantially equivalent to medical devices currently legally marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2000

Mr. Tom Gutierrez
Bird Products Corporation
1100 Bird Center Drive
Palm Springs, CA 92262-8099

Re: K003770
BIRD TBIRD LEGACY VENTILATOR
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: December 5, 2000
Received: December 6, 2000

Dear Mr. Gutierrez:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication For Use

510 (k) Number (if known): K003770 Page 1 of 1

Device Name: TBird Legacy Ventilator

Indication For Use:

The TBird Legacy Ventilator is intended to provide continuous or intermittent mechanical ventilatory support for the care of individuals who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 10 kg (22 lbs.), who require the following general types of ventilatory support, as prescribed by an attending physician:

- Positive pressure ventilation
- Assist/Control, SIMV, CPAP modes of ventilation

The ventilator is suitable for use in institutional and home settings

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003770

Prescription Use X OR Over-The-Counter Use _____
(Per 21 cfr 801.109)

(Optional Format 1-2-96)